



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

McDermott, Will & Emery
Attention: David Rosen, R.Ph., J.D.
600 13th St. N.W.
Washington, D.C. 20005-3096

JUN 13 2000

Docket No. 00P-0913/CP1

Dear Mr. Rosen:

This is in response to your petition filed on March 6, 2000, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Albuterol Sulfate Inhalation Solution, 0.0417%. The listed drug product to which you refer in your petition is Ventolin® (Albuterol Sulfate) Inhalation Solution, 0.5%, manufactured by Glaxo Wellcome, Inc.

Your request involves a change in strength from that of the listed drug product (i.e., from 0.5% to 0.0417%). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength which differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness if the proposed drug product is adequately labeled. Section 505(j)(2)(A) permits changes in labeling required because of differences approved under a petition filed under Section 505(j)(2)(C) of the Act. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

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To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for this drug product prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

Please be advised that formulations of drug products or inactive ingredient changes are not evaluated during the review and approval of the petition. Any changes in formulation or inactive ingredients are evaluated during the review of the ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Gary Buehler", with a stylized flourish at the end.

Gary J. Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research